DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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4/15/2016

OrthoSensor, Incorporated
Ms. Deborah Johnson
Regulatory Affairs Manager
1855 Griffin Road, Suite A-310
Dania Beach, Florida 33004

Re: K150372
Trade/Device Name: VERASENSE Knee System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: ONN
Dated: March 17, 2016
Received: March 18, 2016

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150372

Device Name
VERASENSE Knee System

Indications for Use *(Describe)*

The VERASENSE Knee System is indicated for any medical condition in which primary or revision Total Knee Arthroplasty (TKA) would be indicated.

For use as a tool for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. The VERASENSE Knee System is sterile, for single patient use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Traditional 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92

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Date of Summary: April 14, 2016

Predicate 510(k) Number(s):
K131767 – Orthosensor VERASENSE™ Knee System
K130380 - Orthosensor VERASENSE™ Knee System
K090474 - Orthosensor VERASENSE™ Knee System

Traditional 510(k) Number: K150372

Trade/Proprietary: VERASENSE™ Knee System

Classification Name: Intraoperative Orthopedic Joint Assessment Aid

Product Code: ONN

Device Classification: Class II (21 CFR 882.4560)

Device Description:

The VERASENSE Knee System provides a means to dynamically balance the knee during primary or revision Total Knee Arthroplasty (TKA) intra-operatively. The system includes an instrumented trial tibial insert comprising an array of load sensors that measure the forces applied on its surface and angular positional information (such as alignment, varus/valgus, posterior, and anterior slope positioning, etc.) after insertion into the space between the tibia and femur.

The VERASENSE Knee System is compatible with the following knee implant systems:

- Biomet Vanguard
- Stryker Triathalon
- Zimmer NexGen
- Smith & Nephew Journey II
- Smith & Nephew Legion

Intended Use:

The VERASENSE Knee System is indicated for any medical condition in which primary or revision Total Knee Arthroplasty (TKA) would be indicated.

For use as a tool for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. The VERASENSE Knee System is sterile, for single patient use.

Description of Changes to the Device: The reason for this traditional 510(k) submission is to update the intended use statement.

Technological Characteristics:

The VERASENSE™ Knee System is an intra-operative device for use in primary or revision total knee arthroplasty (TKA), where all patient contacting components are made of biocompatible polycarbonate and adhesive.

The VERASENSE™ Knee System is an intelligent disposable tibial insert that wirelessly transmits the measured data to the OrthoSensor LinkStation for surgeon visualization. Individual VERASENSE™ devices are packaged sterile, for single patient use with a Shim Set for thickness adjustments.

The OrthoSensor LinkStation and VERASENSE™ Knee System Software Application are required for use of the VERASENSE™ Knee System device. The LinkStation

contains a computer and all peripheral equipment required to display the measured data by providing a graphical and numerical presentation of the loads in both the medial and lateral compartments of the knee. VERASENSE™ Knee System devices are implant system specific due to variations in implant design.

Performance Data: N/A

Clinical Data: N/A

Substantial Equivalence:

The VERASENSE™ Knee System is substantially equivalent to the devices previously cleared by FDA in K131767, K130380 and K090474. This equivalency is determined because the VERASENSE™ Knee System has equivalent manufacturing materials, operating principles, and physical, operational specifications as compared to the predicate devices. The similarities and differences between the proposed and predicate devices have been identified and determined that they have no impact on safety or effectiveness.

Summary of Testing: N/A

Conclusion: Based on the predicate comparison, and equivalency assessment, the VERASENSE™ Knee System is substantially equivalent to the predicate device.